Biosimilars

50-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: THE BIOLOGY OF BIOTECH

OVERVIEW

Biosimilars provides an overview of the science, biomanufacturing technology, and regulatory requirements for receiving approval to market biosimilar products. The course begins by taking an in-depth look at the science, specifically how a therapeutic protein's structure dictates its function. With this foundational knowledge, users understand how biomanufacturing conditions can alter a biosimilar, causing it to function differently than its reference product. The course ends with some tested approaches to demonstrating biosimilarity that have been acceptable to the FDA and EMA.

Five Takeaways:

1. Understanding how a protein's structure dictates its function.
2. Ability to discuss how post-translational modifications can change a protein's intended function.
3. A comprehensive understanding of how biosimilars may differ from its reference product once it has been manufactured.
4. FDA and EMA requirements for biosimilar approval and the underlying scientific/quality/regulatory principles involved.
5. General considerations of animal/clinical/in vitro studies, as well as the FDA's Totality-of-the-Evidence approach.

AGENDA

- **Protein Function** reinforces a deep understanding of proteins by describing their various cellular functions through examples. Biosimilars are proteins.
- **Protein Synthesis** explains protein structure and the steps involved in making a protein. By understanding that a protein's structure influences its functions, one can begin to understand how a reference product and biosimilar may not be identical.
- **Post-Translational Modifications** points out that both genes and cells influence the type of post-translational modification and the degree to which the protein is modified. This modification determines if a therapeutic will work or not work.

continued

- **Biologics** list the functions of therapeutic proteins and compares and contrasts biologics with small molecule drugs.
- **Introduction to Biosimilars** reviews the EMA and FDA definitions of biosimilars.
- **The Product Is the Process** lists the steps of biomanufacturing explaining the goal of each step. This section identifies where variations can occur between two identical production campaigns, demonstrating how a biosimilar may not be identical to the reference product. Itemize key formulation parameters and examples of where protein stability testing are highlighted.
- **Biosimilars Safety and Regulation** takes an in-depth look at immunogenicity, a main safety concern of biosimilars. A discussion of how companies test for immunogenicity and predict immune response to a therapeutic protein is given. The course ends by explaining how companies gain approval for a biosimilar.